UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/056,019	04/07/98	TUOMANEN	E 1340-1-017

HM12/0524

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EXAMINER	
ALLEN, M	
ART UNIT	**PAPER NUMBER**
1631	14

DATE MAILED: 05/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/056,019	Tuoman n et al.
Examiner	**Group Art Unit**
Marianne P. All n	1631

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-45* is/are pending in the applicat

Of the above, claim(s) *19-38 and 40-45* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-18 and 39* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-45* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1630, Art Unit 1631.

Applicant's election with traverse of Group I, claims 1-18 and 39 in Paper No. 13 is acknowledged. The traversal is on the ground(s) that there is no significant burden of search, particularly with respect to Group V. This is not found persuasive because burden has been previously established. The search of Group V requires considerations not found in product claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 19-38 and 40-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **with** traverse in Paper No. 13.

The abstract of the disclosure is objected to because it contains multiple paragraphs. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: The specification, particularly the description of the figures, does not reference the appropriate SEQ ID NOS.

Appropriate correction is required.

Claims 9, 12, 14-18, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is viewed as a product by process claim; however, the language of claim 9 is confusing as SEQ ID NO: 24 (see claim 7) does not have 475 amino acids and so it is unclear what product applicant is intending to claim.

Claim 12 recites "said fragments" but there is no antecedent basis for this concept in claim 1.

Claims 14-18 are confusing in that they appear to be duplicative of claims 1-3 and 5-6. The term "immunogenic" in the preamble does not provide any clear structural limitation to the claimed polypeptide. In a product claim the preamble is given no weight.

Claim 39 is directed to a pharmaceutical composition which implies an intended use that is not disclosed within the claim. It is unclear whether this claim is also intended to be directed to a particular amount of polypeptide (i.e. for the intended use) or any amount. Clarification is requested.

Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides of SEQ ID NO: 24 with tertiary structure produced as set forth on page 64, does not reasonably provide enablement for all polypeptides encompassed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification discloses a method of making a particular N-terminal fragment on page 64; however, the specification does not provide any guidance on how to determine tertiary structure (e.g. X-ray crystallography) or how to identify different tertiary structures encompassed by the claims (folded, unfolded, misfolded). With respect to claim 8, this claim language does not exclude other tertiary structures that the native protein may take under different conditions. In addition binding proteins routinely change tertiary structure upon binding to a ligand. The specification disclosure is directed more to retaining a particular function than retaining a particular structure. As such, the specification enables production of the protein which inherently possesses a particular tertiary structure (which is not elaborated upon) but does not enable producing proteins with other unspecified tertiary structures.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 10-18, and 39 are rejected under 35 U.S.C. 102(a) as being anticipated by Masure et al. (WO 97/41151).

SEQ ID NO: 25 of Masure et al. is disclosed as the amino acid sequence of a choline binding protein from Streptococcus pneumoniae. The sequence listing identifies it as an N-terminal fragment. The reference discloses fragments and pharmaceutical compositions (including immunogenic vaccines) of the disclosed CBPs. This sequence has two N-terminal methionines. (See at least abstract, page 50, sequence listing, and claims.) SEQ ID NO: 25 has sequence in common with SEQ ID NOS: 1, 3, 7, and 9 of the instant invention and has the motif of SEQ ID NO: 6 (KXXE). Independent claims 1 and 14 have no structural (sequence) requirements and are being interpreted to include the fragments, mutants, variants, analogs, and derivatives of the dependent claims. (Otherwise the dependent claims would not be properly dependent.) The recitation of "N-terminal choline binding protein A truncate" does not define a particular structure in the absence of a precise definition in the specification. Furthermore, the use of "comprising" is interpreted as encompassing inclusion of additional unrelated sequences and/or full length sequences. As such, SEQ ID NO: 25 and the disclosure of Masure et al. properly anticipate the claims. With respect to claim 13, the reference is silent as to lectin activity and choline binding properties; however, absent evidence to the contrary these properties would be inherent as the structural limitations of the claims have been met.

Claims 1-6, 10-18, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Briles et al. (WO 97/09994).

The protein sequences disclosed by Briles et al. are disclosed as from Streptococcus pneumoniae and include N-terminal fragment. Many have N-terminal methionines. The reference discloses fragments and pharmaceutical compositions (including immunogenic vaccines) of the disclosed proteins. (See at least abstract, claims, and Figures 13, 21, and 22.) These sequences have sequence in common with SEQ ID NOS: 1, 3, 7, and 9 of the instant invention and have the motif of SEQ ID NO: 6 (KXXE). Independent claims 1 and 14 have no structural (sequence) requirements and are being interpreted to include the fragments, mutants, variants, analogs, and derivatives of the dependent claims. (Otherwise the dependent claims would not be properly dependent.) The recitation of "N-terminal choline binding protein A truncate" does not define a particular structure in the absence of a precise definition in the specification. Furthermore, the use of "comprising" is interpreted as encompassing inclusion of additional unrelated sequences and/or full length sequences. As such, the proteins of Briles et al. properly anticipate the claims. With respect to claim 13, the reference is silent as to lectin activity and choline binding properties; however, absent evidence to the contrary these properties would be inherent as the structural limitations of the claims have been met.

Claims 1, 4, 6, 10-14, 18, and 39 are rejected under 35 U.S.C. 102(a) as being anticipated by Hammerschmidt et al. (Molecular Microbiology, 1997).

The sequence for type 47 in Figure 9 of Hammerschmidt et al. has the motif of SEQ ID NO: 6 (KXXE) and contains SEQ ID NO: 9. The figure description identifies it as an N-terminal fragment with an N-terminal methionine. Compositions in pharmaceutically acceptable carriers are disclosed. (See at least abstract and Figure 9.) The recitation of "N-terminal choline binding protein A truncate" does not define a particular structure in the absence of a precise definition in the specification. Furthermore, the use of "comprising" is interpreted as encompassing inclusion of additional unrelated sequences and/or full length sequences. As such, The sequence of Hammerschmidt et al. properly anticipates the claims. With respect to claim 13, the reference is silent as to lectin activity and choline binding properties; however, absent evidence to the contrary these properties would be inherent as the structural limitations of the claims have been met.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 9:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028. Official FAX communications may be directed to either (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER
~~GROUP 1800~~
AU1631